

Long term outcomes of Endoscopic Intermuscular Dissection for stage I rectal carcinomas

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24409

Source

Nationaal Trial Register

Brief title

EID

Health condition

T1 rectal cancer

Sponsors and support

Primary sponsor: UMC Utrecht

Source(s) of monetary or material Support: xxxx

Intervention

Outcome measures

Primary outcome

- 1) The proportion of histology confirmed (R0) resections of deep submucosal (T1) invasive rectal carcinomas with R0 defined as a minimal of 0.1 mm tumor free deep resection margin
- 2) The 3 and 5 years recurrence rate defined as either a local regrowth, LNM during or distant

metastasis during follow-up of an R0 resection of a T1 CRC without the histological risk factors lymphovascular invasion, tumor budding or poor differentiation.

Secondary outcome

- 1) The quality of completion TME surgery after EID
- 2) The proportion curative resections defined as an R0 resection without the histological risk factors lymphovascular invasion, poor (G3) differentiation and/or high grade (BD2-3) tumor budding
- 3) Technical success of the EID in achieving an en bloc resection through the intermuscular plane, leaving the longitudinal muscle layer intact
- 4) Adverse outcomes after EID defined by any EID related AE or mortality within 30 days. The AE will be recorded according the ASGE lexicon.
- 5) All costs of the procedure will be recorded, as well as hospital stay, and re-intervention or re-admission for complications.
- 6) Quality of life (QLQ-C30, QLQ-C29, and EQ-5D-5L)
- 7) Functional outcome (COREFO and LARS score)
- 8) Sensitivity, specificity, negative and positive predictive value will be determined of MRI for making the difference between T1 Sm2-3 versus T2, and nodal staging.

Study description

Background summary

Rationale: With the introduction of the national colorectal cancer (CRC) screening program the number of T1 CRCs have increased. Approximately 80% of these T1 CRCs are located in the sigmoid and rectum. The risk of lymph node metastasis (LNM) is approximately 10-15% for non-pedunculated T1 CRCs in the rectum. Therefore 80% could potentially be cured with a minimal invasive local resection. Achieving a decrease in unnecessary radical rectal surgery is desired, since the long term burden of a total mesorectal excision (TME) on the patient's quality of life is high (stoma, low anterior resection syndrome etc). In the past, deep submucosal invasive cancer (Sm3) was considered a risk factor for LNM, but recent observations showed that in the absence of lymphovascular invasion and tumor budding, the risk of LNM is only 1.3-1.7%, which equals the mortality risk of TME. Endoscopic intermuscular dissection (EID) is a new endoscopic technique designed as an adaptation of the well-known classical ESD technique. Instead of dissecting the lower third of the submucosal space in classical ESD, EID aims to dissect the intermuscular space between the circular and the longitudinal part of the m. propria (instead of the submucosa) in the rectum. In this adaptation EID can achieve a radical resection (R0) for deep submucosal invasive T1 CRCs, thereby potentially obviate the need for radical surgery.

Objective: The aim of this study is to prospectively evaluate the long-term outcome of endoscopic intermuscular dissection for a deep invasive rectal T1 carcinoma.

Study design: Prospective cohort study

Study population: All consecutive adult patients with an endoscopic intermuscular dissection for a suspected deep submucosal invasive T1 rectal carcinoma.

Main study parameters: R0-resection, curative resection rate, local recurrence rate, stoma rate after completion TME, quality of life

Study objective

That intermuscular dissection of polyps suspected of deep submucosal invasive carcinoma can result in the radical (R0) excision of > 85% of the carcinomas, and that the risk of local recurrence is below 4%.

Study design

Recurrence rate at 3 and 5 years

Intervention

Intermuscular dissection between the circular and longitudinal part of the m. propria of the rectum

Contacts

Public

UMC Utrecht
LMG Moons

0614599001

Scientific

UMC Utrecht
LMG Moons

0614599001

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following

criteria:

- Adult patients with a suspected T1 CRC with deep submucosal invasion based on optical diagnosis, using JNET 3, NICO III or Hiroshima C2-C3 classification, or > 40% with the OPTICAL model.
- A T1 rectal cancer located at or under the sigmoid take-off on the MRI
- At least 5 mm between the dentate line and the carcinomatous part of the polyp
- Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Age < 18 years
- Unable to complete quality of life questionnaires at baseline and 1e follow-up, or sign informed consent
- Treatment of a AJCC stage III or IV CRC within the last 5 years
- A suspicious peri-rectal lymph node of > 9 mm on the preprocedural MRI.
- A T1 CRC extending above the sigmoid take-off on MRI

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2020
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8409
Other	METC UMC Utrecht : xxx

Study results